ANNALS OF SURGERY
Vol. 230, No. 6, 800–807

Open *Versus* Laparoscopic Adjustable Silicone Gastric Banding

A Prospective Randomized Trial for Treatment of Morbid Obesity

Laurens T. de Wit, MD,* Lisbeth Mathus-Vliegen, MD,† Coby Hey, MD,‡ Bart Rademaker, MD,‡ Dirk J. Gouma, MD,* and Huug Obertop, MD*

*From the Departments of *Surgery, †Gastroenterology, and ‡Anesthesiology, Academic Medical Center, Amsterdam, The Netherlands*

Objective

To perform the first prospective trial of laparoscopic *versus* open adjustable silicone gastric banding (ASGB) in patients with morbid obesity.

Summary Background Data

Vertical banded gastroplasty has been used for many years to treat morbid obesity, but the size of the stoma has remained a source of failure after the procedure. ASGB has the advantages of maintaining gastric integrity and the potential for readjustment of the band, if needed. It has been suggested that laparoscopic ASGB, recently introduced to reduce postoperative complications and hospital stay, has a negative impact on outcome.

Methods

Fifty patients with morbid obesity of >5 years' duration and a body-mass index (BMI) > 40 kg/m^2 were randomized to undergo laparoscopic or open ASGB. The difficulty of the procedure, surgical time, postoperative complications, and hospital stay were assessed. Stoma adjustments, long-term complications, readmissions, weight loss, and BMI were determined.

Results

All procedures were successfully carried out. Of 25 patients assigned to laparoscopic ASGB, 2 were converted to an open procedure. Surgical time was significantly longer for laparoscopic ASGB (150 minutes *vs.* 76 minutes for open ASGB). There was no difference in complications. Mean hospital stay was 5.9 days for the laparoscopic procedure *versus* 7.2 days for open ASGB ($p < 0.05$). The total number of readmissions (6 *vs.* 15) and overall hospital stay in the first year (7.8 *vs.* 11.8 days) were lower after laparoscopic ASGB ($p < 0.05$). Weight and BMI were reduced significantly in both groups, but there was no difference between the groups.

Conclusion

Laparoscopic and open ASGB were equally effective in terms of early (first-year) weight loss, reduction of BMI, and postoperative complications. The laparoscopic procedure was associated with a shorter initial hospital stay and fewer readmissions during follow-up and is therefore the preferred treatment in morbidly obese patients undergoing ASGB.

Obesity, in particular morbid obesity (defined as an excess weight of more than 100% [or >45 kg above the ideal weight], or a body mass index [BMI] > 40 kg/m^2), leads to high incidence of complications and a decrease in life expectancy.[1] The obesity-related complications are caused by an increased incidence of cardiovascular disease, hypertension, diabetes mellitus, hyperlipidemia, cholelithiasis, renal disease, arthrosis, sleep apnea, and psychosocial problems.

Previous studies showed that patients benefit from weight loss by an increase in life expectancy, improvement in the quality of life, and reduction of social isolation. Some of the comorbidities disappear with adequate weight loss.[2–6]

Medical weight-reduction treatments include dieting, behavioral therapy, psychotherapy, drug therapy, physical ex-

Presented at the Sixth Annual Meeting of the European Surgical Association, at the Royal College of Surgeons of England, London, United Kingdom, April 23–24, 1999.
Correspondence: Laurens T. de Wit, MD, Academic Medical Center, Dept. of Surgery/G4-115, Meibergdreef 9, 1105 AZ Amsterdam, The Netherlands.
Accepted for publication July 1999.

ercise, placement of gastric balloons, and even jaw wiring. Because of the disappointing results of medical treatment, surgical therapies have been developed. The so-called bariatric surgery deals with weight-reduction procedures in obese and morbidly obese patients. It started with the jejunoileal bypass, but restrictive gastric procedures proved to be better than bypass procedures, which can cause severe malabsorption problems. The vertical banded gastroplasty developed by Mason combined good results with few complications and is the standard procedure thus far.[7,8]

The main problem with these restrictive procedures is the size of the stoma; a few millimeters too wide will lead to a failure of the procedure in terms of weight reduction. Banding of the stomach was already a well-known procedure, but it gained interest with the development of adjustable silicone gastric banding (ASGB). The main differences compared with vertical banded gastroplasty are the maintenance of gastric integrity and the possibility of readjustment of the band. Early results are promising, although other authors have mentioned more complications, such as leakage of the reservoir, pouch dilatation, and band migration.[9]

Laparoscopic introduction of the gastric banding is a recent development. Some of the advantages of laparoscopic ASGB compared with open ASGB might be a reduction in wound complications and a reduction in respiratory problems because of better postoperative ventilation and early mobilization.[10] Potential disadvantages related to the laparoscopic approach might be the occurrence of pneumothorax. Negative influences on cardiac output and hypercapnia have also been mentioned. It has also been suggested that the anticipated shorter hospital stay with the laparoscopic approach, with less medical supervision and dietary guidance, may hinder outcome and weight reduction.[10]

The potential advantages and disadvantages of the laparoscopic and open procedures have never been evaluated in a prospective trial. Consequently, we designed a prospective randomized study to compare the efficacy of both methods, assuming there would be no difference between the methods in terms of the effect on weight loss. We analyzed whether the laparoscopic approach could lead to a reduction in complications (*i.e.*, wound and pulmonary problems) and the hospital stay. Secondary procedures, readmissions, access port, and long-term complications during the first year of follow-up were also assessed.

PATIENTS AND METHODS

The study design was a randomized controlled trial. Approval was obtained from the hospital ethics committee before the start of the trial.

Patients

Recruitment of patients was performed at the gastroenterology outpatient clinic by one of the senior investigators (LMV); it started in November 1995 and concluded in February 1997. The indication for ASGB was a history of obesity of >5 years' duration, BMI > 40 kg/m^2, documented weight-loss attempts in the past, and good motivation for surgery. The age had to be 18 to 55 years. Patients with previous gastric surgeries, large hiatal hernias, alcohol abuse, pregnancy, psychiatric disease (*e.g.*, bulimia) or treatment, and hormonal or genetic obesity-related diseases were not considered eligible for the study and were excluded.

Patients were considered eligible by the gastroenterologist after evaluation of hematology, blood chemistry, hormonal status, electrocardiogram, gastroscopy, a barium meal, and ultrasound of the gallbladder. The anesthesiologist could subsequently refuse admittance of the patient in the trial if a high risk was associated with anesthesia. Next, the surgeon was consulted and had to agree that the patient was suitable for both procedures. The nature and purpose of the study were explained to the patient, and informed consent was obtained. Patients were then randomly allocated by computer at the Department of Clinical Epidemiology on the day of surgery for either laparoscopic or open placement. Stratification was performed for sex and BMI.

Sex, age, weight and height, anthropometry (skin fold measurements, waist/hip ratio), medical history, including history of obesity and previous attempts of weight loss, current medications, and the patient's treatment expectations, eating behavior pattern, and psychological profile were recorded on entry to the study.

Surgical Procedures and Anesthesia

One surgeon (LTdeW) operated on all patients, and two anesthesiologists (CH, BR) were responsible for the perioperative care. The procedure was performed under general anesthesia, and all patients were given cefuroxin 1.5 g intravenously. At the end of the procedure, control of leakage was performed by methylene blue through the nasogastric tube, and all patients underwent a gastrography within 48 hours of surgery. The nasogastric tube was removed immediately after extubation. Patients were allowed to go home as soon as they felt able to do so.

Open Procedure

The patient is placed in supine position. Using a midline incision from xiphoid to umbilicus, the abdomen is opened. A retractor is placed under the costal cartilage to obtain a wide access to the upper abdominal cavity. First, the gastrohepatic ligament is opened 1.5 cm below the esophagogastric junction, close to the lesser curvature of the stomach. Using blunt dissection, a retrogastric route close to the stomach is obtained. The gastrophrenic ligament is opened close to the greater curvature 1.5 cm under the esophagogastric junction and just cranial from the short gastric vessels. The omental bursa is not opened. The inflatable band (BioEnterics Corp.) is now guided around the stomach and partly closed.

The anesthesiologist introduces a nasogastric calibration tube with a 15-ml balloon and a pressure sensor at its distal end for calibration. The pressure sensor is connected to the Gastrostenometer for calibration. After this, the inflated balloon is pulled up high in the stomach, and the inflatable band is completely closed around the tip of the tube. The band is filled with saline until the Gastrostenometer points to 4. The total amount of fluid necessary is noted, and the band is deflated (noting the amount of fluid taken out). The band is fixed at the stomach with three or four interrupted sutures at the greater curvature. The inflation tube is led out of the abdomen through a small transrectal incision. The reservoir is connected and buried in the rectus musculature. The overlying fascia is closed. The abdomen is closed with an uninterrupted suture (PDS). The band is adjusted only on demand (*i.e.*, for insufficient weight loss).

Laparoscopic Procedure

The patient is placed in a modified lithotomy position and, after pneumoperitoneum is induced, five trocars (10 to 11 mm) are positioned in the upper abdomen. First, the gastrohepatic ligament is opened close to the lesser curvature of the stomach, 1.5 cm below the esophagogastric junction and medial to the gastric vessels. This maneuver permits a curved instrument to be introduced in the retrogastric space. By blunt dissection, the tip of the instrument is advanced toward the upper part of the greater curvature, taking care that this tip emerges in the avascular gastrophrenic ligament just cranial to the first short gastric vessels, and not opening the lesser sac. The inflatable band is introduced into the abdominal cavity, guided into place around the stomach, and partly closed. Completion of closure and calibration are performed as described for the open procedure.

The band is fixed at the stomach with three or four interrupted sutures at the greater curvature. The inflation tube is led out of the abdomen through the 18-mm trocar, which is then removed. The reservoir is connected and then buried in the rectus musculature. The reservoir is fixed to the overlying fascia, which is then closed. The band is adjusted only on demand.

Outcome Assessment

The surgical findings and the difficulty of the procedure were scored by the surgeon using a visual analogue scale (1, an easy procedure; 10 = a procedure that could not be performed or had to be converted). The surgical time (time between skin incision and closure of the wound) and complications were recorded. Recorded complications included wound infections, abscess, wound dehiscence, bleeding, sepsis, gastric perforation, cardiovascular, pulmonary, and thromboembolic complications, and urinary tract infection. Hospital stay and in-hospital deaths were also assessed.

The gastroenterologist performed the follow-up for the first year at week 1, 4, 8, 11, 16, 20, 24, 36, and 52. In case of stoma adjustments or other surgery-related long-term sequelae, patients were also seen by a surgeon to deflate or refill the band under fluoroscopic control, or to perform other complication-related procedures (*e.g.*, drainage of an abscess, closure of a hernia). Long-term complications, additional procedures, readmissions, hospital stay, weight loss, and reduction of BMI were evaluated.

Statistical Analysis

The sample size calculation of the study was based on the assumption that both methods (open and laparoscopic ASGB) are equally effective in weight reduction, considering a difference of 10% of weight acceptable and clinically not important. The estimated weight loss is 40 kg. An equivalence sample size in this case implies that 25 patients in each group will be sufficient with an α of 0.05 and a power β of 0.2.

For the hospital stay, the sample size calculation was based on the assumption that a reduction in hospital stay could be expected from 8 days after open ASGB to 4 days after laparoscopic ASGB. This difference was considered clinically relevant. A sample size of two groups of 12 patients is needed to prove a significant difference in hospital stay (α 0.05, β 0.1).

Randomization was necessary because the groups would be too different in these small sizes of sample and the bias in selection would be too high. Patients were grouped by BMI: 40 to 45, 45 to 50, and greater. Randomization was performed using a program developed at the Department of Clinical Epidemiology of the Academic Medical Center. The Mann-Whitney test was used to compare the data of the two study groups, taking into consideration its normal distribution. A difference of <0.05 (two-sided test) was considered significant.

RESULTS

Patients

From November 1995 to February 1997, 50 patients were randomized to either laparoscopic ASGB (group 1, n = 25) or open ASGB (group 2, n = 25). The two groups were comparable in sex, age, mean weight, BMI, and laboratory test results (Table 1).

The procedure could be carried out adequately in all patients. In group 1, two patients underwent conversion from laparoscopic to open procedure because of inability to obtain pneumoperitoneum (resulting from extensive adhesions in one patient and hepatomegaly in another).

In group 1, two patients underwent cholecystectomy for gallstones. In group 2, five patients underwent cholecystectomy for asymptomatic stone disease. In another seven patients in group 2, the gallbladder was punctured to obtain bile samples for study purposes unrelated to this trial. No complications occurred after these punctures.

Table 1. DEMOGRAPHIC DATA AND LABORATORY RESULTS

Parameter	Laparoscopic ASGB (n = 25)	Open ASGB (n = 25)	p Value
Sex ratio (M/F)	8/17	8/17	NS
Weight (kg)	152.2 ± 31.4	146.4 ± 19.9	NS
BMI	51.3 ± 10.4	49.7 ± 5.6	NS
Hypertension	4	2	NS
Diabetes mellitus	3	0	NS
Gastroesophageal reflux	1	2	NS
Serum creatinine (μmol/l)	58.3 ± 10.2	57 ± 7.5	NS
Blood glucose (mmol/l)	6.9 ± 2.6	5.6 ± 1.2	NS
Alkaline phosphate (U/l)	75 ± 17.5	79.2 ± 17.1	NS
ASAT (U/l)	25.6 ± 13.4	22.4 ± 8.5	NS
O_2 saturation (%)	95.7 ± 4.3	96.3 ± 1.9	NS

Data are given as mean ± SD.

The surgical time was significantly longer in group 1 than in group 2 (150 *vs.* 76 minutes). The difficulty of the procedure, according the visual analogue scale, was significantly higher for the laparoscopic procedure (Table 2). The early postoperative complications were not different, but the mean hospital stay was significantly shorter in the laparoscopic group (5.9 *vs.* 7.2 days, $p = 0.05$).

Follow-Up

After 1 year, one patient (group 2) was lost to follow-up. Long-term complications were classified into general surgical complications and access port complications. There was no difference in surgical complications in the groups (Table 3), but incisional hernias were more common in group 2 (seven incisional hernias in three patients). Access port complications are summarized in Table 3. No difference was found between the groups. All patients with complications were readmitted for treatment. In the patient with a migrated band, the band was removed by laparotomy, the stomach was closed with interrupted sutures, and the patient recovered uneventfully. The number of readmissions (6 *vs.* 15) and the total hospital stay during the first year (7.8 *vs.* 11.8 days) for groups 1 and 2, respectively, were significantly different ($p < 0.05$).

Table 3. FIRST-YEAR COMPLICATIONS, READMISSIONS, AND OVERALL HOSPITAL STAY

Parameter	Laparoscopic ASGB (n = 25)	Open ASGB (n = 24)	p Value
Surgical Complications			
Incisional hernia	—	7 (3 pts)	NS
Migration band	—	1	NS
Umbilical hernia	1	—	NS
Access Port Complications			
Total	7 (5 pts)	6 (5 pts)	NS
Dislocation	2	1	NS
Dislodgment	5	4	NS
Infection	—	1	NS
Replacement	5	4	NS
Hospital Stay			
Patients readmitted	5	7	NS
Total readmissions	6	15	<0.05
Overall hospital stay in days (mean ± SD)	7.8 ± 6	11.8 ± 10.5	<0.05

Preoperative weight, weight after 1 year, and BMI are summarized in Table 4. In both groups, there was a significant mean reduction in weight (35 kg in group 1, 34.4 kg in group 2). There was no difference in weight reduction

Table 2. SURGICAL FINDINGS, PROCEDURAL DIFFICULTY, EARLY POSTOPERATIVE COMPLICATIONS, AND HOSPITAL STAY

Parameter	Laparoscopic ASGB (n = 25)	Open ASGB (n = 25)	p Value
Conversion	2	—	
Cholecystectomy	2	5	
Adhesiolysis	1	—	
Gallbladder puncture	—	7	
Difficulty of the procedure (1–10) (range)	4.7 ± 2.1 (3–10)	3.8 ± 1.1 (3–7)	<0.05
Surgical time (minutes) (mean ± SD)	150 ± 48	76 ± 20	<0.05
Pulmonary complications (infection/atelectasis)	2	2	
Urinary infection	2	—	
Rhabdomyolysis	1	—	
Neurologic complication (neuropraxia)	1	1	
Perforation pouch	—	1	
Wound abscess	—	1	
Fever	—	2	
Gout	—	1	
Days in hospital (mean, range)	5.9 (4–10)	7.2 (5–13)	<0.05

Table 4. WEIGHT AND BMI BEFORE AND 52 WEEKS AFTER SURGERY

	Laparoscopic ASGB (n = 25)	Open ASGB (n = 24)	p Value
Weight before surgery (kg)	152.2 ± 31.4	146.4 ± 19.9	NS
Weight 52 weeks after surgery (kg)	117.2 ± 25.2	112.0 ± 19.1	NS
Weight loss (kg)	35	34.4	
BMI before surgery (kg/m^2)	51.3 ± 10.4	49.7 ± 5.6	NS
BMI 52 weeks after surgery (kg/m^2)	39.7 ± 8.7	39.1 ± 8.2	NS

All values are expressed as mean ± SD.
p value of difference before and 52 weeks after is < 0.05.

between the groups (Fig. 1). BMI was also reduced significantly after both procedures; again, no difference in reduction was found between the groups.

DISCUSSION

This study demonstrates that both open and laparoscopic ASGB can be performed safely as surgical treatment for morbid obesity, without any deaths and with an acceptable rate of complications. The complication rate is in accordance with other studies, and, remarkably, no significant difference in early postoperative complications between the open and laparoscopic procedures was found.[9–13] The claimed advantages of the laparoscopic ASGB—reduction of respiratory complications and wound infection—were not found in this study. Pulmonary problems occurred in two patients in both groups and wound infection in, respec-

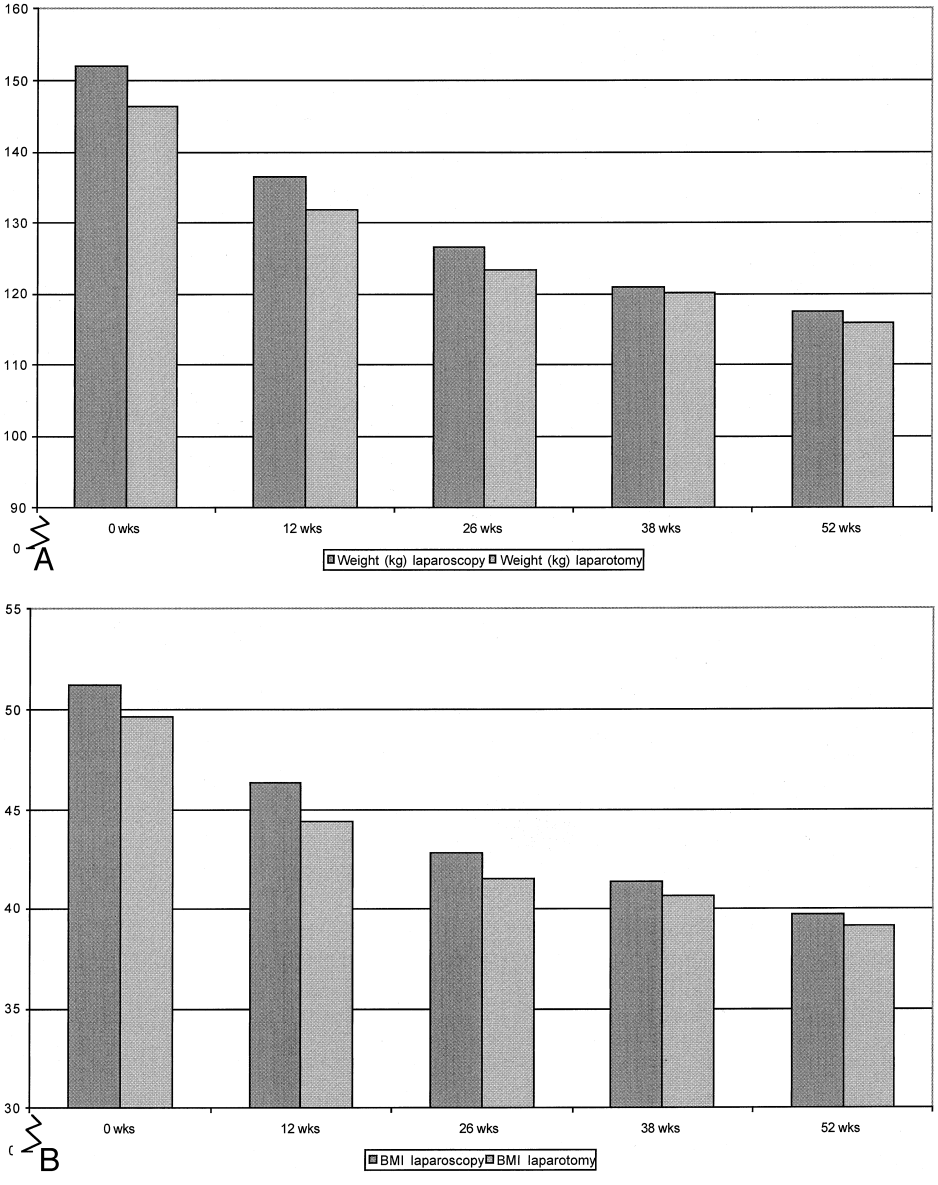

Figure 1. Reduction of weight (A) and BMI (B) in patients who underwent laparoscopic (n = 25) and open (n = 25) ASGB for morbid obesity.

tively, 0 and 1 patients. The wound infection rate after open surgery was lower than could be expected in this group of high-risk patients.

The laparoscopic procedure was associated with a shorter hospital stay (6 *vs.* 7 days), but the pretrial assumption that hospital stay would be reduced from 8 to 4 days could not be verified. As previously reported in other trials comparing open and laparoscopic surgery, the hospital stay for patients undergoing the open procedure in this trial was shorter than reported before the laparoscopic era.[10] The trial probably influenced the hospital stay of the open procedure.

Pneumothorax, a potential disadvantage of the laparoscopic procedure, was not found in the present series nor in the study of Belachew et al.[10] In that series of 350 patients, the hospital stay was not mentioned, probably because the Belgian National Health Insurance program does not limit hospital stay. It was suggested in that study that a shorter hospital stay could have a negative effect on outcome because of limited time for dietary education and psychological support.

In the present study, no difference in weight reduction was found between the two procedures (mean weight reduction after 1 year of 35 and 34.4 kg, respectively). This is in accordance with other studies and is also comparable with weight loss after vertical banded gastroplasty.[5,8] The incidence of late complications, such as incisional hernia and complications of the access port, were not different between the groups (zero *vs.* three patients, and five *vs.* six patients, respectively). The number of readmissions and overall hospital stay in the first year were significantly higher after open ASGB. The Belgian study found that 82% of the late complications occurred during the learning phase (first year after starting this new technique).[10]

In another series, most pouch dilations were found to occur within the first 2 years, with the bulk of this problem occurring within 1 year (median 8.5 months).[14] No pouch dilatation was found in the present study. This is probably because the omental bursa was not opened during the procedure, and the band was located above the omental bursa through a narrow canal $\leq$ 1.5 cm in diameter, created behind the proximal stomach. In earlier studies and in the original description of the technique, the bursa was always opened, creating a chance for the stomach to slip through.[11–13]

Follow-up is far too short to evaluate the final outcome in terms of weight loss. However, the weight-loss curves and reduction in BMI during the first year are in accordance with other studies.[9,10,13]

The aim of this study was to evaluate the efficacy of the laparoscopic and open procedures in terms of early complications within the first year. It has been suggested that patients with morbid obesity are at risk for symptomatic gallstone disease after surgery, and that cholecystectomy should be performed routinely because it does not lead to an increase in complications or a prolonged hospital stay. We decided to perform a cholecystectomy in all patients with gallstones in this study. No complications occurred because of that strategy.

CONCLUSION

The outcome of patients who underwent ASGB, in terms of postoperative complications and early (first-year) weight loss, appeared not to be influenced by whether the procedure was performed using an open or a laparoscopic approach. Laparoscopic ASGB was associated with a shorter hospital stay and fewer readmissions. Laparoscopy is therefore the preferred approach in morbidly obese patients undergoing ASGB.

Acknowledgment

The authors thank the data management center of the Department of Clinical Epidemiology for randomization of the patients.

References

1. Kral JG. Morbid obesity and related health risks. Ann Intern Med 1985; 103:1043–1047.
2. Charuzi I, Lavie P, Peiser J, Peled R. Bariatric surgery in morbid obese sleep-apnea patients: short- and long-term follow-up. Am J Clin Nutr 1992; 55:594S–596S.
3. Gleysteen J. Results of surgery: long-term effects on hyperlipidemia. Am J Clin Nutr 1992; 55:591S–593S.
4. Sugerman HJ, Fairman RP, Sood RK, et al. Long-term effects of gastric surgery for treating respiratory insufficiency of obesity. Am J Clin Nutr 1992; 55:597S–601S.
5. Carson JL, Ruddy ME, Duff AE, et al. The effect of gastric bypass surgery on hypertension in morbid obese patients. Arch Intern Med 1994; 154:193–200.
6. Pories WJ, Swanson MS, MacDonald KG, et al. Who would have thought it? An operation proves to be the most effective therapy for adult-onset diabetes mellitus. Ann Surg 1995; 222:339–352.
7. NIH conference. Gastrointestinal surgery for severe obesity. Ann Intern Med 1991; 115:956–961.
8. Benotti PN. Editorial: vertical banded gastroplasty in the treatment of severe obesity. Mayo Clin Proc 1991; 66:862–864.
9. Favretti F, Enzi G, Pizzirani E, et al. Adjustable silicone gastric banding (ASGB): the Italian experience. Obes Surg 1993; 3:53–56.
10. Belachew M, Legrand M, Vincent V, et al. Laparoscopic adjustable gastric banding. World J Surg 1998; 22:955–963.
11. Kuzmak LI. A review of seven years' experience with silicone gastric banding. Obes Surg 1991; 1:403–408.
12. Forsell P. The Swedish adjustable gastric banding for morbid obesity: nine-year experience and a four-year follow-up of patients operated with a new adjustable band. Obes Surg 1997; 4:345–351.
13. Belachew M, Jacquet P, Lardinois F, Karler C. Vertical banded gastroplasty *versus* adjustable silicone gastric banding in the treatment of morbid obesity: a preliminary report. Obes Surg 1993; 3:275–278.
14. O'Brien P, Brown W, Smith A, et al. Prospective study of a laparoscopically placed, adjustable gastric band in the treatment of morbid obesity. Br J Surg 199; 86:113–118.

Discussion

PROF. B. MILLAT (Montpellier, France): As the first randomized trial comparing laparoscopic *versus* open silicone gastric banding,

this paper is of outstanding interest. At first sight, the conclusion could be that when SGB is indicated for control of morbid obesity, the laparoscopic approach is preferred because of shorter initial hospital stay and fewer readmissions during a 1-year follow-up. SGB was equally effective in weight reduction when performed laparoscopically or with an open approach. Incisional morbidity is the pitfall of open bariatric surgery. I would like to make the following comments regarding this study.

Firstly, evidence that surgically induced weight reduction in the morbidly obese is associated with an increase of their life expectancy is still lacking. So far, bariatric surgical procedures are only weight-reduction procedures. In the present study, 1 year after operation the body-mass index in both groups was still at the 40 kg/m^2 limit, the very definition of the level for obesity-related increased morbidity. In other series, the maximum weight reduction observed after SGB was reached 12 to 18 months postoperatively.

Secondly, the popularity of SGB has increased due to its laparoscopic feasibility and to the potential reduction of surgery-associated morbidity when compared to open procedures. Open SGB, however, is not the most efficient procedure in term of weight reduction when compared to the Mason or gastric bypass techniques. Reducing the relative risk of complications by the laparoscopic technique is not a foolproof demonstration that, due to the overwhelming widespread diffusion of the laparoscopic SGB, the total number of patients with postoperative complications will not actually increase, sometimes with complications more severe than with the open technique.

Thirdly: What is the clinical significance of a 4-day increase in mean hospital stay in patients facing a life-long health care problem? Hospital stay is a measurement of medical productivity but not necessarily a demonstration of the quality of care. Time spent in the operating room for the LASGB was more than twice the operative duration for the open procedure. When comparing OR and ward costs in the U.S. system, one hour in the OR is equivalent to a 2-day hospital stay—though in the present study the mean increase of 74 minutes in the OR was not compensated by a mean 1.3-day decrease in initial hospital stay.

Lastly: As one of the aims of bariatric surgery is to reduce incision-related morbidity, one possibility seems to be the laparoscopic approach, but another could be to take into account information collected from randomized trials showing potential benefits of paramedian or transverse incisions *versus* midline incisions, of continuous nonabsorbable *versus* absorbable sutures, and of temporary reinforcement with polyglactin mesh for the prevention of incisional hernias in obese patients.

The future of bariatric surgery might be the laparoscopic Mason technique, or a reduction of the incisional morbidity of open procedures. But the true question is, is the future of morbid obesity surgical or pharmacological?

DR. T. DE WIT (Amsterdam, The Netherlands): Thank you for your remarks. I have to agree with all of them. However, I can add something to them.

Point 1: There is still no evidence if bariatric surgery in the long end is beneficial. I hope that the ongoing Scandinavian long-term study, of which the preliminary results are quite promising, will give some answers in due time. In most studies, the mean BMI before surgery was just above 40 and after 18 months dropped just over 10 points. In our study, this was around 50. In 1 year the BMI dropped 10 points, so I think we are in line with the other studies, but it will last a little longer.

Point 2: Time will tell if SGB is as good or as bad as the Mason or the bypass procedure. The concept of adjustment is in theory a benefit compared to the gastroplasty. Our main fear is the problem of band migration as an equivalent to the problems in the past with the antireflux surgery. Up until now, the highest incidence reported is $<5\%$, and that is still far less than the Angelchik prosthesis.

Point 3: The mean operation time in the laparoscopic group was much higher. The main cause is the learning curve. In the last cohort of the group, operation time was much shorter (some within 90 minutes, including cholecystectomy), and it is reported that the procedure itself can be done within 1 hour.

Point 4: We use the midline incision in the Netherlands because we are accustomed to it in bariatric surgery, but indeed the transverse incision diminishes the risk of incisional hernia.

PROF. U. HAGLUND (Uppsala, Sweden): The results of this study (longer OR time, a technically more difficult operation but shorter hospital stay) are what could be expected from other studies comparing a laparoscopic approach with conventional open surgery. For more detailed study of the difference between the two techniques, a much larger number of patients and a much longer follow-up are certainly needed. The problem that should be addressed, however, is not if adjustable banding should be performed by an open or a laparoscopic technique, but if it should be performed at all! To study this issue, one needs a longer follow-up period and more active follow-up than reported in this study. The main problem with adjustable gastric banding is migration into the stomach, a potentially life-threatening complication that probably occurs equally often following laparoscopic as open banding. Many institutions, including ours, have stopped doing adjustable banding operations because of the unacceptably high frequency after 5 to 10 years. In addition, severe reflux esophagitis is a common complication to this procedure. Therefore, many institutions have reported a reoperation frequency $>$ 20% within a couple of years, a figure many consider unacceptable. However, these patients are difficult to follow up and tend to deny these problems, hoping to remain thinner.

My questions, then, are: 1) Have you in the follow-up of these patients used routine upper gastrointestinal endoscopy? and 2) What is your experience with band migrations in the further follow-up?

DR. DE WIT: I fully subscribe to your hesitation to adjustable banding. It was not our intention to discuss the therapy in itself, but since the introduction of the adjustable band there is an increase in the number of weight-reduction operations in the Netherlands. Our goal was to study if laparoscopy really has the advantages over open surgery as reported by authors up until now, without a proper prospective randomized study. Of course we will have to follow this group much longer than 1 year, but because the bulk of the postoperative complications reported are apparent within 1 year, we found it justified to report these data now. To answer your questions: All the patients underwent an upper GI radiological investigation and gastroscopy after 1 year. Secondly, up until now, we have one band migration in this group. After removal of the band, the patient recovered uneventfully. We have experience with band migration in two other patients who were referred to us. After removal, these patients also recovered uneventfully.

PROF. A. JOHNSON (Sheffield, United Kingdom): May I congratulate you on conducting this excellent trial. Twenty-five patients in each group is a small number. Were power calculations made before you started? Did you cost the two procedures, because double the time in the operating theater would more than overcome the saving of just over a day in hospital? I was interested in your problem with the access ports. Were they all sutured in position?

DR. DE WIT (Closing Discussion): Thank you for your kind remarks. Indeed, power calculations were made before this study. Assuming there would be no difference in weight loss after the two procedures, the calculation showed that two groups of 25 was enough to reach equivalence. We assumed that a reduction in hospital stay from 8 to 4 days could be accomplished. To prove this, 2×12 patients were needed. We did not cost the procedures.

All access ports were buried in the right upper rectal muscle and held in place with three nonresorbable sutures. The biggest problem was dislodgment of the connection of the tube to the port itself. The connection between the catheter of the band to the tube of the port was a lesser problem.

Morbid obesity is a multifactorial disease and therefore the therapy has to be multidisciplinary. A team of dedicated professionals is necessary and should consist of a surgeon, gastroenterologist, anesthetist, as well as a psychologist. The personnel in the operating theater and on the ward have to be specially equipped to handle these patients. At this moment, we lack the right therapy for every patient. Certainly, surgery is not always the best choice.